EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2022
EMA/37943/2022

Administrative Arrangement

With regard to temporary measures related to COVID-19 vaccines authorised for use in the Union and the service provided by the Agency to a Member State for creating and reporting Individual Case Safety Reports (ICSRs) to EudraVigilance (hereinafter the 'Arrangement')

Between the **European Medicines Agency** (hereinafter also referred to as 'the Agency' or 'EMA'), and

Slovakia (**Štátny ústav pre kontrolu liečiv**) (hereinafter referred to as 'MS' or 'Member State'),

Each of them referred to hereinafter as a 'Party' and collectively referred to as 'Parties',

for the purpose of implementing temporary measures related to COVID vaccines and the support to be provided by the Agency to National Competent Authorities in Member States in the creation of Individual Case Safety Reports (ICSRs) and the reporting to EudraVigilance.

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency thereof (hereinafter Regulation (EC) No 726/2004);

Having regard to Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001 on the Community code relating to medicinal products for human use (hereinafter, Directive 2001/83/EC),

Having regard to Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council thereof;

Having regard to the Guideline on good pharmacovigilance practices (GVP) - Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev. 2) as adopted in accordance with Article 108a of Directive 2001/83/EC;

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council, of 23 October 2018, on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (hereinafter, Regulation (EU) 2018/1725), and in particular Article 28 thereof;

Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the

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free movement of such data, and repealing Directive 95/46/EC (hereinafter, Regulation (EU) 2016/679), and in particular Article 26 thereof.

Whereas:

(1) Article 107(a)(1) of Directive 2001/83/EC establishes that each Member State shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 102(c) and (e).

(2) Article 107(a)(4) of Directive 2001/83/EC establishes that Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database. They shall, within 90 days from the receipt of reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database. Marketing authorisation holders shall access those reports through the Eudravigilance database;

(3) Article 24(1) of Regulation (EC) No 726/2004 establishes that the Agency shall, in collaboration with the Member States and the Commission, set up and maintain a database and data processing network (hereinafter the 'Eudravigilance database') to collate pharmacovigilance information regarding medicinal products authorised in the Union and to allow competent authorities to access that information simultaneously and to share it.

(4) This Arrangement has been agreed by the Member State and the Agency to address the substantial increase of reports of suspected adverse drug reactions (ADRs) as a result of the COVID-19 vaccination campaigns conducted by the Member State in response to the coronavirus pandemic situation.

Have agreed as follows:

1. Scope of this arrangement

1.1. This Arrangement sets out the allocation of respective roles and practical arrangements between the Parties for the purpose of the processing of suspected adverse reactions related to COVID-19 vaccines authorised for use in the Union that were reported by patients and healthcare professionals to the respective Member State.

1.2. This Arrangement refers to a temporary measure, for a period of 12 months during which the Agency shall, as instructed by the Member State, create Individual Case Safety Reports (ICSRs) for the purpose as set out under point 1.1. The Agency shall create the ICSRs in accordance with the internationally agreed formats and standards set out in chapter IV of Commission Implementing Regulation (EU) No 520/2012 and make these ICSRs available to the Member State for reporting to the EudraVigilance database in accordance with Article 107(b) of Directive 2001/83/EC. The Agency shall not be responsible for the Member State's compliance with the reporting timelines set out in the same Article.

1.3. For the purpose of this Arrangement, the definitions laid down in Article 1 of Directive 2001/83/EC, respectively, shall apply.

1.4. For the purpose and the duration of this Arrangement, the Member State will - at the latest prior to the commencement of activities under this Arrangement - indicate (i.e. select by marking below) which of the options - Option A or Option B will apply to it under this Arrangement:

☒ Option A

or

☐ Option B.

1A. Option A

1.A.1. The processing operation consists of the processing activities performed by the Party responsible for that task:

1.A.1.a) At the start of the operation, the Member State instructs the Agency in writing:

i. which of the personal data contained in the electronic copies of the suspected adverse reaction (ADR) reports from patients and healthcare professionals shall be redacted;

ii. of the database(s) to which the created ICSRs shall be submitted electronically i.e.,

- the EudraVigilance database, or
- the pharmacovigilance database of the Member State (based on receiver identifier registered in the EudraVigilance database), or
- both, the EudraVigilance database and the pharmacovigilance database of the Member State.

Furthermore, the Member State provides the Agency with a "frequently used terms and acronyms sheet" including commonly used phrases/terms in adverse reaction reporting to facilitate the ADR report processing.

1.A.1.b) The Member State sends electronic copies of reports of suspected adverse reactions ("source data") they received from patients and healthcare professionals in batches and in a secure manner to the Agency using EudraLink. Each batch submission shall include a list of either world-wide unique case identifiers or a code number for each case and a prescribed format for the world-wide unique case identifier to be used for the creation of ICSRs.

1.A.1.c) The Agency securely stores the electronic copies and make them available in batches to the Agency's contractor[1] through a Virtual Desktop Interface (VDI) operated by the Agency.

1.A.1.d) The Agency, through its contractor[2] and using the web-application EVWEB, creates ICSRs in accordance with the internationally agreed formats and standards as set out in in chapter IV of the Commission Implementing Regulation (EU) No 520/2012. The language to be used in free text fields will be the language of the source data and English.

1.A.1.e) The Agency grants its personnel access to the data to the extent strictly necessary for the implementation, management and monitoring of this Arrangement. The Agency ensures that personnel authorised to process personal data has committed itself to

[1] Contract EMA/2019/15/BD - Data Management
[2] Contract EMA/2019/15/BD - Data Management

confidentiality or is under appropriate statutory obligation of confidentiality in accordance with the provisions of Article II.8.

1.A.1.f) For the purpose of the creation of ICSRs, the Member State authorises the personnel of the Agency's contractor to act as EVWEB users of the respective Member State.

1.A.1.g) The Agency, through its contractor[3], shares at regular intervals a spreadsheet, which lists the worldwide unique case identification numbers with the Member State.

1.A.1.h) The Member State - within a time period of 15 days of the receipt of the spreadsheet referred to under point g) above - reviews the created ICSRs to ensure personal data are redacted as specified under point a) and meet the quality parameters as set out in GVP Module VI and the "Detailed proposal on temporary reduction of data processing in ICSRs for National Competent Authorities during COVID-19 pandemic"[4].

1.A.1.i) Following completion of the creation of ICSRs for a specific batch, the Agency removes the completed batch(es) from the VDI and load the next batch(es). The Agency deletes each completed batch after 15 calendar days with the exception where the Member State raises a potential data quality issue in writing with the Agency prior to the expiry of the 15 calendar days.

1B. Option B

1.B.1. The processing operation consists of the processing activities performed by the Party responsible for that task:

1.B.1.a) At the start of the operation, the Member State instructs the Agency in writing:

i. which of the personal data contained in the electronic copies of the suspected adverse reaction (ADR) reports from patients and healthcare professionals shall be redacted;

ii. of the pharmacovigilance database(s) in which the ICSRs shall be created.

Furthermore, the Member State provides the Agency with a "frequently used terms and acronyms sheet" including commonly used phrases/terms in adverse reaction reporting to facilitate the ADR report processing.

1.B.1.b) For the purpose of the creation of ICSRs, the Member State authorises the personnel of the Agency's contractor to act as pharmacovigilance database users of the respective Member State. The Member State shall ensure that there are enough accounts for the Agency's contractor's personnel and for a secure connection between the Agency's contractor and the Member State.

1.B.1.c) The Member State provides training in the use of the specified pharmacovigilance database to the Agency's contractor's personnel.

1.B.1.d) The Agency, through its contractor[5] and using the pharmacovigilance database specified by the Member State, creates ICSRs in accordance with the internationally agreed formats and standards as set out in chapter IV of the Commission Implementing Regulation (EU) No 520/2012. The language to be used in free text fields will be the language of the source data and English.

[3] Contract EMA/2019/15/BD - Data Management
[4] EMA/708541/2021
[5] Contract EMA/2019/15/BD - Data Management

1.B.1.e) The Agency, through its contractor, shares at regular intervals a spreadsheet, which lists the worldwide unique case identification numbers with the Member State.

1.B.1.f) The Member State - within a time period of 15 days of the receipt of the spreadsheet referred to under point e) - reviews the created ICSRs to ensure they meet the quality parameters as set out in GVP Module VI and the "Detailed proposal on temporary reduction of data processing in ICSRs for National Competent Authorities during COVID-19 pandemic[6]".

2. Data Protection Provisions

2.1. This chapter sets out the allocation of respective roles, responsibilities and practical arrangements between the Parties for compliance with their respective data protection obligations under Regulation (EU) 2018/1725 and Regulation (EU) 2016/679, when carrying out processing operations of personal data of data subjects.

2.2. For the purpose of this Arrangement, the definitions laid down in Article 3 of Regulation (EU) 2018/1725 and Article 4 of Regulation (EU) 2016/679, respectively, shall apply.

2.3. This Arrangement governs the processing of personal data as necessary for the activities carried out in accordance with, amongst others, the activities described in the scope of this Arrangement (chapter 1.1.).

2.4. For the purpose of this Arrangement,

i. the Member State shall be considered as 'controller' within the meaning of point (8) of Article 3 of Regulation (EU) 2018/1725 and point (7) of Article 4 of Regulation (EU) 2016/679, respectively;

ii. the Agency shall act as 'processor' within the meaning of point (12) of Article 3 of Regulation (EU) 2018/1725 and point (8) of Article 4 of Regulation (EU) 2016/679, respectively.

2.A Processing of personal data by the Agency

2.A.1. The processing of personal data by the Agency for the purposes set out in this Agreement shall meet the requirements of Regulation (EU) No 2018/1725.

2.A.2. The localisation of and access to the personal data processed by the Agency as part of this Agreement needs to comply with the following:

i. the personal data shall be processed within the territory of the European Union and the European Economic Area and will not leave that territory;
ii. the data shall only be held in data centres located with the territory of the European Union and the European Economic Area;
iii. any transfer of personal data under this Arrangement to third countries or international organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU)2018/1725.

2.A.3. The Agency assists the controllers for the fulfilment of the controller's obligation to respond to requests for exercising rights of person whose personal data is processed in relation to this Agreement as laid down in Chapter III (Article 13-23) of Regulation (EU) 2016/679. The Agency's assistance is fulfilled by informing without delay the controller about such requests.

[6] EMA/708541/2021

2.A.4. As regards the use of EudraLink and EVWEB, the Agency adopts appropriate technical and organisational security measures, giving due regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing, in order to ensure, in particular, as appropriate:

i. the redaction of personal data based on the instructions received by the respective Member State and encryption of personal data;
ii. the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
iii. the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
iv. a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
v. measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

2.A.5. The Agency will notify relevant personal data breaches to the controller without undue delay and at the latest within 48 hours after the Agency becomes aware of the breach. In such cases, the Agency will provide the controllers with at least the following information:

i. nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
ii. likely consequences of the breach;
iii. measures taken or proposed to be taken to address the breach, including, where appropriate, measures to mitigate its possible adverse effects.

2.A.6. The Agency will immediately inform the controller if, in its opinion, an instruction infringes Regulation (EU) 2018/1725, Regulation (EU) 2016/679, or other Union or Member State data protection provisions.

2.A.7. The Agency maintains a record of all data processing operations carried on behalf of the controller, transfers of personal data, security breaches, responses to requests for exercising rights of people whose personal data is processed and requests for access to personal data by third parties.

2.A.8. The Agency is subject to Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union, particularly as regards the inviolability of archives (including the physical location of data and services) and data security, which includes personal data held on behalf of the controller in the premises of the Agency or the Agency's contractor.

2.A.9. The Agency will notify the competent authority of the Member State without delay of any legally binding request for disclosure of the personal data processed on behalf of the controller made by any national public authority, including an authority from a third country.

2.A.10. The duration of processing of personal data by the Agency will not exceed the period of 12 months. Upon expiry of this period, the Agency shall effectively delete all personal data unless Union or national law requires a longer storage of personal data.

2.B Responsibilities of the controller

2.B.1. In order to guarantee compliance with applicable data protection rules, the controller complies with the general principles of data protection, as laid down in Article 4 of Regulation (EU) 2016/679, respectively.

2.B.2. The controller complies with its obligations as an individual controller to inform data subjects about the processing of their personal data.

2.B.3. As regards the use of national pharmacovigilance database(s) of the Member State, the Member State adopts appropriate technical and organisational security measures, giving due regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing, in order to ensure, in particular, as appropriate:

i. the redaction of personal data and encryption of personal data;
ii. the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
iii. the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
iv. a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
v. measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

2.B.4. The Agency will notify relevant personal data breaches to the controller without undue delay and at the latest within 48 hours after the Agency becomes aware of the breach. In such cases, the Agency will provide the controllers with at least the following information:

i. nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
ii. likely consequences of the breach;
iii. measures taken or proposed to be taken to address the breach, including, where appropriate, measures to mitigate its possible adverse effects.

2.B.5. The controller handles data subject requests raised in connection with this Agreement in accordance with their internal process and applicable data protection requirements.

3. Effective Date

This Arrangement has been agreed by the duly authorised representatives of the Parties with the understanding that all Parties agree to comply with it prior to, and as a condition to, starting the service from 26 January 2022 onwards.

Should any amendments to this Arrangement become necessary, this will follow the adoption procedure involving representatives of the Parties as referred to in this Arrangement.

This Arrangement is effective as of 23 January 2022 and shall expire on 31 December 2022.

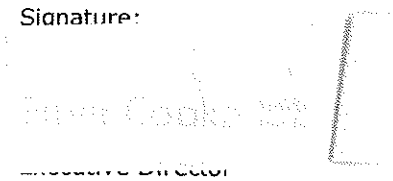
Date:

Signature:

Štátny ústav pre kontrolu liečiv

Date:

Signature:



Executive Director

European Medicines Agency (EMA)